1. Historical Overview

The use of percutaneously introduced prosthetic devices to maintain the luminal integrity of diseased blood vessels was initially proposed by Charles Dotter in 1964, who speculated that the temporary use of a silastic endovascular splint might maintain an adequate lumen after the creation of a pathway across a previously occluded vessel.[1] Dotter and colleagues were also the first to apply the term *stent* for vascular implants in their description of an experimental technique for the non-surgical endarterial placement of tubular coiled-wire grafts in the femoral and popliteal arteries of healthy dogs.[2] The etymology of the word "stent" is unclear. It has been associated with a device to hold a skin graft in position, with a support for tubular structures being anastomosed, and with an impression of the oral cavity made from Stent's mass. Stent's mass was concocted by Charles Thomas Stent (1807–85), an English dentist who developed it to form an impression of the teeth and oral cavity[3,4] (figure 1.1). Stent, as applied to endovascular scaffolding devices, may also have its origins from the verb "to stint", which means "to restrain within certain limits". The early stents used by Dotter were mounted coaxially on a guidewire and positioned with a pusher catheter. Since the pre- and post-implantation stent dimensions were identical, the graft diameter was limited by the size of the arteriotomy and the approach vessel, and only small coils could be passed percutaneously. Although these stents could be properly positioned, stent dislocations and significant narrowing within the stented segments occurred. These problems temporarily bridled any optimism that such a device might find clinical application in the treatment of vascular diseases.

In 1983, two preliminary reports showed the feasibility of transcatheter arterial grafting, and rekindled interest in the non-surgical placement of endovascular prostheses.[5,6] Using coil wire stents made of nitinol, a unique alloy of titanium and nickel, Dotter and colleagues[5] (figure 1.2) and Cragg and colleagues[6] (figure 1.3) described encouraging results of their transcatheter endoluminal placement in canine arteries. Nitinol has a unique heat-sensitive "memory", which allowed the coil stent to be compressed or straightened at room temperature and introduced through a catheter. When positioned properly, the coils were warmed to body temperature or higher. This caused the metal to lose its malleability, and allowed the stent to return to its initial configuration. These devices successfully maintained vessel patency at 4 weeks in

Figure 1.1: *Charles Stent (1845–1901), an English dentist who lent his name to a tooth mould (bottom) and perhaps to endoluminal scaffolding devices.*

non-heparinized dogs. The work established the potential for the use of such a device in the non-surgical treatment of vascular disease, and was the catalyst for experimentation with a variety of innovative devices.

Not long after the preliminary reports on the use of nitinol coils, Maass and colleagues[7] reported the results of implantation of expanding steel spiral springs in the aortae and vena cavae of dogs and calves. With the application of torque, the springs decreased in diameter, to allow distal delivery. On release of the tension the springs expanded to their predetermined dimensions (figure 1.4). Although the spirals remained stable and did not cause perforation, thrombosis,

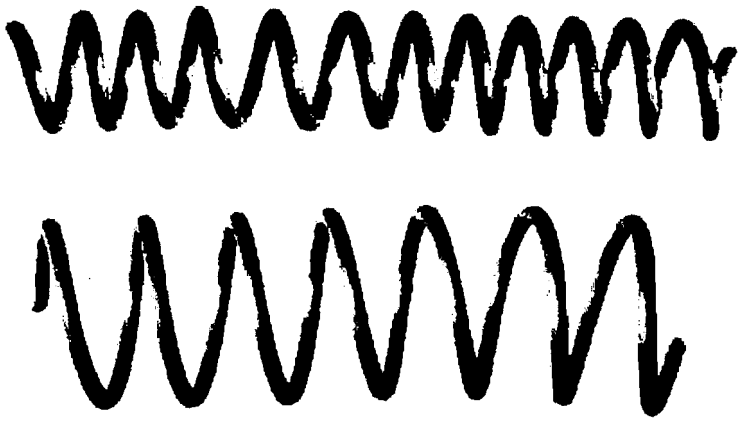

Figure 1.2: *Nitinol coil wire stent. Top: compacted for transcatheter placement. Bottom: same coil after heat-induced (60 °C) reversion to initial, anatomically indicated configuration. (From Dotter CT, Buschmann PAC, McKinney MK, Rösch J. Transluminal expandable nitinol coil stent grafting: preliminary report. Radiology 1983; 147: 259–60.)*

Figure 1.3: *Loosely wound nitinol coil graft. Arrow indicates a threaded adapter which can be attached to a modified guidewire. The coil was straightened in ice water and passed via a catheter into the aorta. The coil reformed when heated to body temperature and could be positioned using the attached guidewire. (From Cragg A, Lund G, Rysavy J, Casteneda F, Casteneda-Zuniga W, Amplatz K. Nonsurgical placement of arterial endoprostheses: a new technique using nitinol wire. Radiology 1983; 147: 261–63.)*

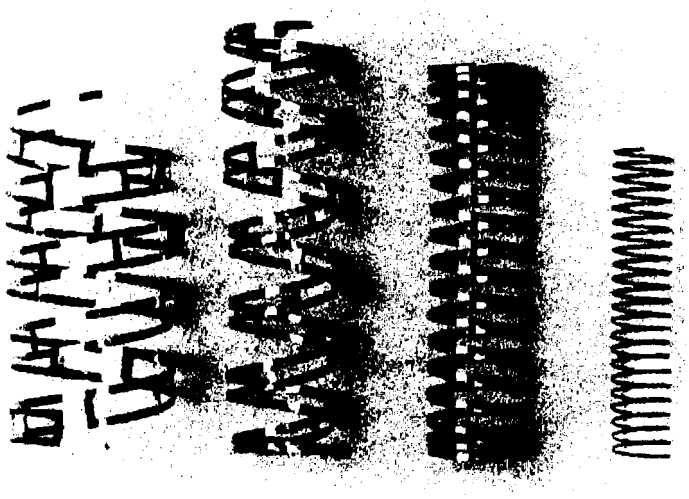

Figure 1.4: *Various types of implanted spiral springs. The devices were made of corrosion resistant heat-treated spring steel alloy. Application of torque to the spiral springs in the direction of the coils increased the number of coils and reduced the diameter of the spiral. (From Maass D, Zollikofer CL, Largiadèr F, Senning A. Radiological follow-up of transluminally inserted vascular endoprostheses: an experimental study using expanding spirals. Radiology 1984; 152: 659–63.)*

or stenosis of the treated vessel, a large diameter applicator was needed for introduction and placement, and this limited target lumen access. In 1985, the initial results of the implantation of spring-loaded self-expanding stents in dogs were described by Gianturco and colleagues[8] (figure 1.5). That research showed the importance of oversizing the stent in relation to the size of the target vessel to prevent migration of the prostheses.

The idea of a balloon-mounted stent for simultaneous dilatation and stent delivery was introduced by Palmaz and colleagues.[9] In 1985, they described preliminary results of the implantation of a balloon expandable stainless-steel wire mesh in canine peripheral arteries. The device was made from 150 μm and 200 μm diameter continuous woven stainless-steel wire. The cross-points of the wire mesh were soldered with silver to give the device a relatively high resistance to radial collapse (figure 1.6). The following year, Palmaz published data on a larger group of 18 balloon expandable stent implantations in canine femoral, renal, mesenteric, and carotid arteries.[10] These early results foretold problems that would plague intravascular stent implantation over the following decade.

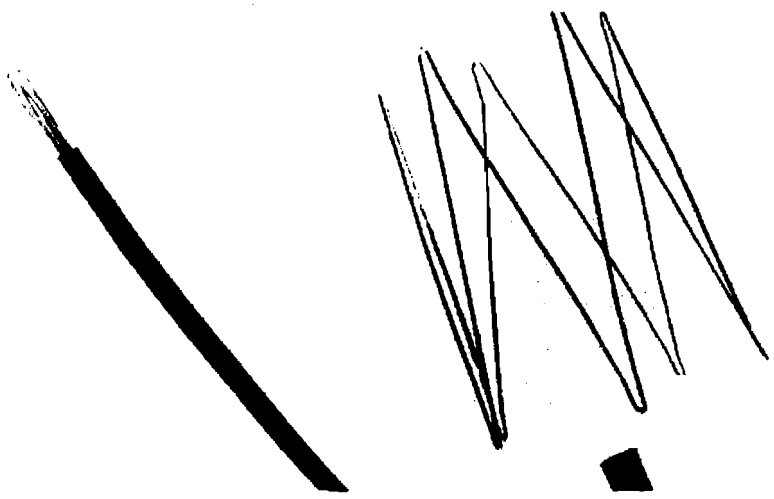

Figure 1.5: Zigzag expanding stainless steel stent. (a) Collapsed stent beginning to exit 12 F Teflon sheath. (b) Stent fully expanded after being pushed from the sheath. (From Wright KC, Wallace S, Charnsangavej C, Carrasco CH, Gianturco C. Percutaneous endovascular stents: an experimental evaluation. Radiology 1985; 156: 69–72.)

Four thrombotic occlusions occurred in the first group of treated animals, which showed that adequate antithrombotic and antiplatelet therapy was needed at the time of stent deployment. Palmaz's group recognized that heparin therapy did not prevent late occlusion of stented segments with low flow, and that the best results were obtained in those without flow restriction. These are now axioms of contemporary stenting. Their observation of an overall patency rate of 77% at 35 weeks was surprisingly similar to the findings of subsequent stent trials.

With the refinement of equipment, smaller vessels could be accessed, and application of stent technology to the coronary system became possible. In 1987, Rousseau and colleagues[11] tested a flexible, self-expanding stainless-steel mesh stent that was restrained with a protective sheath. Forty-seven devices were implanted in 28 dogs, 21 of these devices in coronary arteries. No anticoagulant or antiplatelet agents were used, and partial or total thrombotic occlusion was seen in eight (35%) animals. Thrombus formation occurred at points of rapid reduction of vessel diameter, when the end of the prosthesis impinged upon a side branch of a major vessel and when there was a high ratio of unconstrained (maximal expansion) to implant device diameter. Endothelialization and incorporation of the stent into the vessel wall by neo-intimalization occurred by

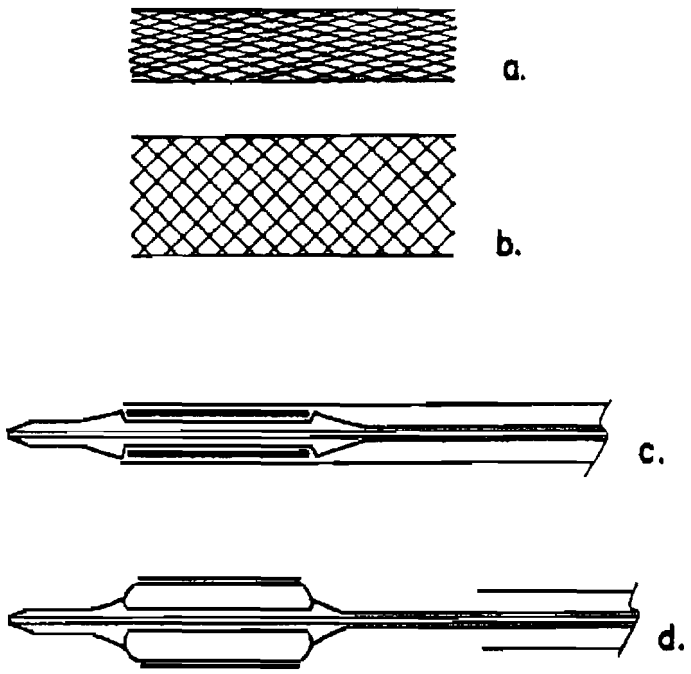

Figure 1.6: *Schematic profile of the balloon expandable wire mesh stent of Palmaz and colleagues in the collapsed (a), and expanded (b) state. The mounted stent was protected from being dislodged off the balloon by oversized leading and trailing retainers (c) and balloon inflation expanded the graft (d). (From Palmaz JC, Sibbit RR, Reuter SR, Tio FO, Rice WJ. Expandable intraluminal graft: a preliminary study. Radiology 1985; 156: 73–77.)*

the third week after implantation. This was consistent with previously reported results of stainless-steel stents.[8,9]

The feasibility of the implantation of balloon expandable stents into canine coronary arteries was also shown in 1987. Roubin and colleagues[12] described implantation of a balloon mounted interdigitating flexible coil stent with a novel design in 39 animals (figure 1.7). Schatz and colleagues[13] reported their results of the percutaneous implantation of a non-articulated modified Palmaz-type stent in the coronary circulation of 20 dogs. The stent was cut with staggered, parallel, rectangular slots from a stainless-steel tube, and was more streamlined than the wire-mesh Palmaz stent (figure 1.8). No thrombotic events were observed in these animals. The publication of these two studies in the cardiovascular literature rather than in a radiological journal showed that coronary stenting had become separated from the field of vascular radiology.

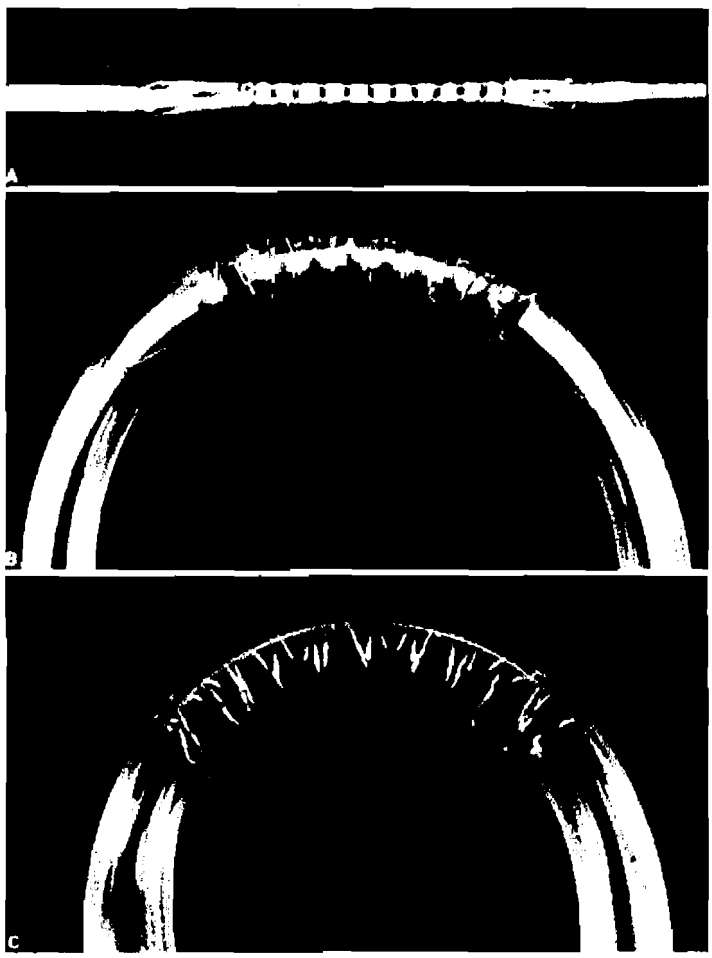

Figure 1.7: *(a) Coil stent coil wrapped firmly on standard PTCA balloon catheter. (b) Stent fully expanded by inflated balloon catheter demonstrated in transparent flexible tubing. (c) Fully expanded stent after removal of deflated balloon catheter. (From Roubin GS, Robinson KA, King III SB, et al. Early and late results of intracoronary arterial stenting after coronary angioplasty in dogs. Circulation 1987; **76:** 891–97.)*

The early experience of Rousseau's group with the implantation of the self-expanding stent in coronary arteries was the impetus for the implantation of a stent in an atheromatous human coronary artery. The first human implantation was done by Jacques Puel (Toulouse, France) in 1986,[14] followed shortly by Ulrich Sigwart (Lausanne, Switzerland). Subsequently, Sigwart, and colleagues[15]

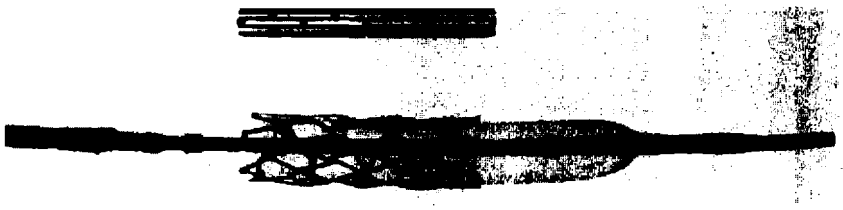

Figure 1.8: *Balloon expandable intravascular stent. Collapsed, the stent fits over any standard coronary angioplasty catheter. Inflation of the balloon results in expansion of each rectangular slot into a diamond configuration. (From Schatz RA, Palmaz JC, Tio FO, Garcia F, Garcia O, Reuter SR. Balloon-expandable intracoronary stents in the adult dog. Circulation 1987; 76: 450–57.)*

reported the results of the implantation of 24 self-expanding mesh stents (Medinvent SA, Lausanne, figure 1.9) in the coronary arteries of 19 patients. Three conditions were considered indications for stent insertion:

- restenosis of a segment previously treated with angioplasty;
- stenosis of aortocoronary-bypass grafts;
- acute coronary occlusion secondary to intimal dissection following balloon angioplasty.

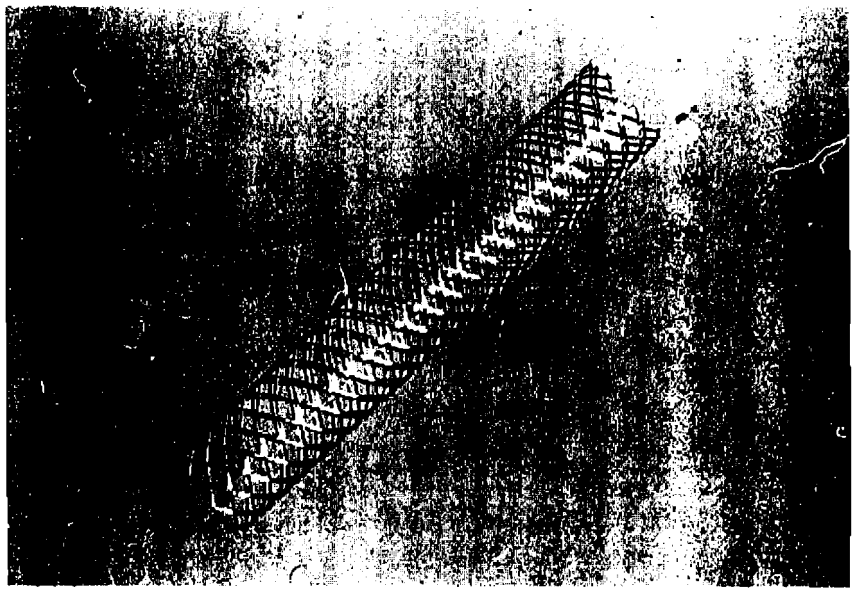

Figure 1.9: *The initial design of the Wallstent used in the early clinical studies. The first stents were made from a stainless-steel alloy with a self-expanding mesh design.*

Two complications related to stent thrombosis occurred (11%) and there were no cases of restenosis within the stented segment 9 weeks to 9 months after implantation. As a consequence of the encouraging results of this landmark study, the US Food and Drug Administration (FDA) gave their approval for phase I trials in the United States. The trials used the balloon expandable Gianturco–Roubin™ and Palmaz–Schatz™ intracoronary stents.

By early 1988, 117 self-expanding intravascular stents, of a type subsequently called the Wallstent™, had been implanted in native coronary arteries (n = 94) or in aortocoronary-bypass grafts (n = 23) of 105 patients.[16] Stents were placed for dilation of a restenosis, acute vessel occlusion after angioplasty, chronic occlusion after angioplasty, and as an adjunct to primary angioplasty. The results of intermediate term follow-up of this first series were sobering. Four patients died before repeat angiography, there was complete stent occlusion of 27 stents in 25 (24%) patients, and a long-term restenosis rate of 14% in those stents that remained patent.[16] The overall mortality rate at 1 year was 7.6%. The results also fuelled the controversy that surrounded the choice of a suitable anticoagulation regimen to minimize postprocedural complications and haemorrhagic side effects. Together with the comments of a daunting editorial that accompanied the manuscript[17] these results diminished the initial optimism for the future of these new devices.

The potential benefit of intracoronary stenting for the treatment of acute and threatened closure complicating percutaneous transluminal coronary angioplasty was demonstrated by Roubin and colleagues.[18] They reported on their experience during 1987–89 using the balloon-expandable Gianturco–Roubin™ stent, which was designed specifically for the control of dissection and acute closure. Stents were successfully deployed in all of the 115 patients studied, and optimum results were obtained in 93% of the patients. Despite the emergent nature of the procedures, the number of complications was low, with 4.2% of cases requiring CABG, an overall myocardial infarction rate of 16%, a subacute thrombosis rate of 7.6%, and an in-hospital mortality rate of 1.7%. These results suggested that stenting for acute or threatened closure limited the need for emergency CABG and reduced the incidence of myocardial infarction. The high incidence of restenosis (41%), similar to rates seen in acute closure successfully managed by balloon dilatation alone, indicated that the stent gave no benefit to late outcome when used for the treatment of acute closure.

More favorable were the results of a multicentre registry of elective stent placement in native coronary vessels (1987–89), presented in 1991 by Schatz and colleagues.[19] Their study compared the implantation of balloon expandable intracoronary stents of two different configurations; the prototypical rigid Palmaz-type stent, and an articulated Palmaz–Schatz™ stent fashioned with a bridging strut between two shorter stainless-steel slotted tubes (figure 1.10). In this study 21% of patients had total occlusion, and 69% had a previously

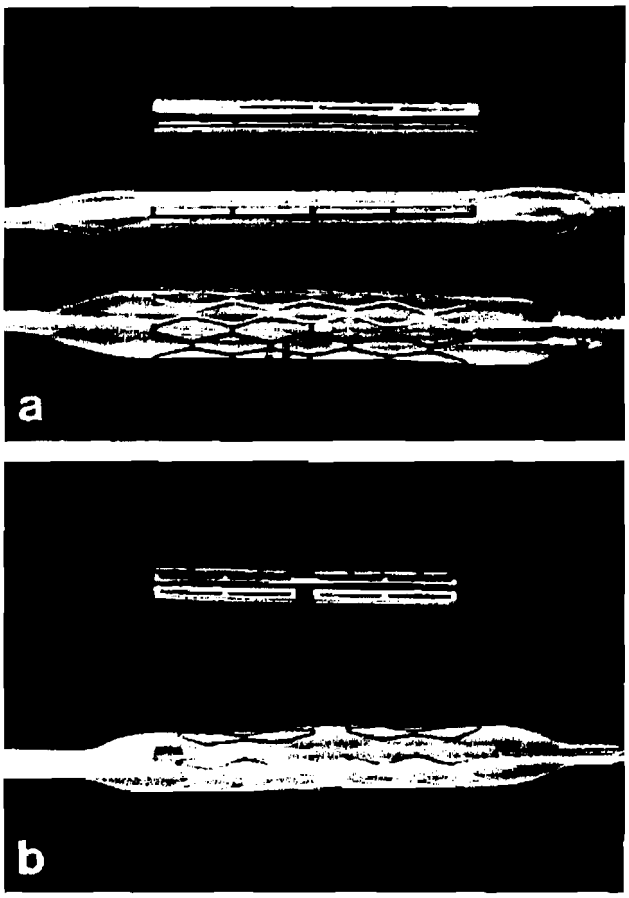

Figure 1.10: *(a) Prototype Palmaz balloon expandable rigid intracoronary stent. (b) Articulated Palmaz-Schatz stent.*

successful coronary angioplasty with clinical and angiographic restenosis. Successful delivery of 299 stents was accomplished in 230 lesions in 213 (93%) patients. Failed delivery occurred with 22 stents, 11 of which were successfully withdrawn, three partially deployed, and eight embolized systemically after failed withdrawal. Two anticoagulation regimens were used. The first 17 stented patients were given procedural dextran and heparin, and discharged on aspirin and dipyridamole only. No episodes of abrupt closure were seen in these patients. Thereafter, as more patients were treated a significant number of thrombotic episodes occurred. Warfarin was added to the postprocedural

regimen after the first 35 patients were treated. In the 174 patients stented thereafter, warfarin was administered and continued for 1–3 months. This procedural change brought a dramatic reduction in the incidence of occlusive thrombosis (0.6%). This low incidence of subacute thrombosis could not be confirmed in a retrospective analysis reported by Haude and colleagues[20] in the same year, which used the same device. In the latter study, a subacute thrombosis rate of 14% was reported, although the studies were not directly comparable in terms of selection of patients. Restenosis rates determined at follow-up angiography were 36% in the registry series of Schatz,[21] and 27% in the work of Haude and colleagues.[20] A higher restenosis rate was seen in those lesions treated with multiple stents[21,22] and in those with a history of restenosis in the stented segment.[21]

The first trial to focus specifically on stent implantation for the treatment of restenosis after angioplasty was published in 1992.[22] In this article, de Jaegere and colleagues[22] described their experience with the Medtronic Wiktor™ stent, a unique coil-like prosthesis made of a single loose interdigitating tantalum wire. Stents were successfully implanted in 59 patients. Thrombotic stent occlusion occurred in 10% of the treated patients, all of whom subsequently suffered a myocardial infarction. The restenosis rate, defined as a change in diameter stenosis of greater than 50% at follow-up, was 29%.

Taken together, these early observational trials highlighted problems with the use of stents. Subacute stent thrombosis was clearly a problem despite the very aggressive anticoagulation regimens used in several of the studies. Rigorous anticoagulation resulted in a longer hospital stay, and in bleeding complications that were difficult to control and occasionally serious. Restenosis of the stented segment was also a problem, with restenosis rates comparable to those seen with angioplasty alone. Nonetheless, these technical obstacles to stent deployment helped to define ideal stent characteristics (table 1.1).

Several fundamental questions were raised by these and other small observational trials. Were the disparate results from the various stent registries related to the clinical circumstances that dictated stent implantation, or were they due to properties inherent in the particular device? Was there a clinical situation for which stenting could provide the solution? After these early trials, the utility of stenting for the treatment of obstructive coronary artery disease remained to be proven.

These pioneer investigators were convinced that coronary stenting could become a standard therapeutic modality in interventional cardiology, through improved periprocedural management of patients, better selection of patients, and clearly defined clinical indications. Their convictions led to the initiation of two major important randomized trials comparing balloon angioplasty with elective Palmaz–Schatz coronary stenting. The European BENESTENT[23] and the North American STRESS[24] studies both began recruitment of patients in 1991. In

Table 1.1 Desirable stent characteristics

Flexible
Trackable
Low unconstrained profile
Radio-opaque
Thromboresistant
Biocompatible
Reliably expandable
High radial strength
Circumferential coverage
Low surface area
Hydrodynamic compatibility

both studies, patients were randomized to conventional balloon angioplasty or to implantation of a Palmaz–Schatz stent in a primary lesion of a native coronary artery with a length of less than 15 mm and a diameter stenosis of 50% (BENESTENT) or 70% (STRESS). A total of 516 patients (257 balloon, 259 stent) all of whom had stable angina, were recruited in the BENESTENT study: 407 patients (202 balloon, 205 stent), of whom 47% had unstable angina symptoms, were randomized in the STRESS study. The incidence of restenosis, according to the 50% diameter stenosis criterion, was significantly lower after stent implantation (BENESTENT 22%, STRESS 32%) than after balloon dilatation alone (BENESTENT 32%, $p = 0.02$, STRESS 42%, $p = 0.046$). Importantly, this difference was associated with a more favourable long-term clinical outcome in patients who received a stent. The 7-month event-free survival in the BENESTENT trial was 79.9% after stenting and 70.4% after balloon angioplasty ($p < 0.05$). In the STRESS study, the comparable figures were 80.5% and 76.0% respectively (difference not significant). The benefits of stent implantation compared with balloon angioplasty were largely due to a reduced need for reintervention in the stent group. The observed benefit came at a cost, however, with stented patients experiencing increased vascular and bleeding complications, and needing a longer hospital stay. One-year follow-up

results of the BENESTENT trial showed a continued benefit for stented patients, with a 1-year event-free survival of 76.8% compared with 68.5% in the balloon angioplasty patients.[25] These two landmark trials conclusively showed that the elective placement of intracoronary stents significantly reduced the incidence of angiographic restenosis in patients with discrete, de-novo lesions in large target vessels. Paradoxically, the BENESTENT and STRESS trials were accepted by clinicians as being positive overall, despite a subacute occlusion rate of 3.7% (which was higher than with balloon angioplasty alone), longer hospitalization times, and more vascular and bleeding complications.

With the publication of the BENESTENT and STRESS trial results and the resultant acceptance of coronary stenting as a promising alternative to angioplasty, attention was then given to improving technical aspects of stent implantation, optimizing adjunctive therapy, and minimizing complication rates. Thrombosis within the self-expanding stainless-steel Medinvent stent, as seen in the early animal experiments,[9] prompted the use of intracoronary urokinase along with heparin, aspirin, dipyridamole, and coumadin in the first human coronary implants.[15] Despite this very aggressive anticoagulation regimen, thrombosis remained a problem. The addition of dextran and sulphinpyrazone[16] increased the number of anticoagulation agents to seven, which led to inevitable bleeding and vascular complications, and a prolonged hospital stay. The high early occlusion rates with these devices[16,17] suggested that stents were highly thrombogenic foreign bodies, and this discouraged investigators from using coronary stents as a primary treatment for coronary artery stenosis. However, Antonio Colombo and his group[26–28] focused attention on the modalities of stent deployment, and questioned the dogma of the intrinsic thrombogenic nature of the stents. The major contribution of these investigators was to assume that the normalization of the rheology inside the stent, as well as its inflow and outflow, would render the anticoagulation treatment superfluous. Intravascular ultrasound imaging had a pivotal role in revealing that most of the angiographically satisfactory stent implantations were far from optimum.[26,27] Incomplete stent apposition, persistence of residual luminal narrowing because of incomplete or asymmetrical stent expansion, and the presence of significant disease of the proximal and distal reference segments could not be easily detected with angiography, and required intravascular ultrasound for visualization. With the use of additional high-pressure non-compliant balloon angioplasty to expand the stent fully, and with stent deployment guided by intravascular ultrasound, Colombo and colleagues progressively decreased the postintervention anticoagulation regimen, and finally stopped it altogether. The procedure had a very low closure rate and a similarly low incidence of vascular complications.[28] Using a strategy of stent deployment largely influenced by the Colombo approach, a multicentre French trial[29] initiated in 1992 examined the feasibility of stenting without postprocedural vitamin-K antagonists and without mandatory ultrasound. With

combined aspirin–ticlopidine antiplatelet therapy and subcutaneous low molecul weight heparin treatment, these researchers observed a significant reduction in the rate of subacute thrombosis. These results have been validated in a larger multicentre European prospective observational trial.[30] Neumann and colleagues[31] observed that platelet markers rather than the coagulation parameters indicated the risk of stent thrombosis. This finding supports the use o antiplatelet rather than anticoagulant postprocedural management. The benefits of combined antiplatelet therapy compared with anticoagulant treatment after coronary stenting were confirmed by the pivotal prospective randomized Intracoronary Stenting and Antithrombotic Regimen (ISAR) trial[32] which showed that aspirin plus ticlopidine therapy reduced haemorrhagic and vascular complications, and the incidence of cardiac events.

Today, full antiplatelet therapy, without additional subcutaneous heparin and without ultrasound guidance, has become routine clinical practice. Using this approach, acute and subacute closure rates have become acceptably low, althougl the search for a better antiplatelet agent continues, and the problem of restenosis remains. All currently available stents are made of metal, and induce significant intimal hyperplasia. New approaches are being tested in order to solve the problem of restenosis, including coatings for metallic stents, stents made of biological materials, biodegradable stents, drug-eluting stents, and radioactive stents. With continued developments and refinements, coronary stenting will remain an integral part of interventional cardiology.

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